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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/688,305	10/17/2003	Martin P. Vacanti	07917-168001 / UMMC 02-32	8886
23579	7590	10/23/2006	EXAMINER DAVIS, RUTH A	
PATREA L. PABST PABST PATENT GROUP LLP 400 COLONY SQUARE SUITE 1200 ATLANTA, GA 30361			ART UNIT 1651	PAPER NUMBER

DATE MAILED: 10/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/688,305

Applicant(s)

VACANTI ET AL.

Examiner

Ruth A. Davis

Art Unit

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 02 August 2006.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) 1-17, 23, 26, 27 and 29-32 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 18-22, 24, 25, 28, 33 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

Applicant's response filed on August 2, 2006 has been received and entered into the case. Claim 1 – 33 are pending; claims 1 – 17, 23, 26 – 28, 29 – 32 are withdrawn from consideration; claims 18 – 22, 24 – 25, 28 and 33 have been considered on the merits. All arguments have been fully considered.

### ***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 18 – 22, 24 – 25, 28 and 33 stnad rejected under 35 U.S.C. 102(b) as being anticipated by Vacanti et al. (US 5716404).

Applicant claims a living biological matrix comprising a spore like cell, cell fragments, lipids and polysaccharides; a component that adds shape, structure, or support to the matrix; a hydrogel or adhesive; and a cellular component selected from fibronectin, laminin, collagen, glycoprotein, thrombospondin, elastin, fibrillin, mucopolysaccharide, glycolipid, heparin sulfate, chondroitin sulfate, keratin sulfate, glycosaminoglycan, and hyaluronic acid. Applicant additionally claims a living biological matrix produced by obtaining a cell sample, disrupting the cell sample to create a mixture of cells and cellular debris, culturing the mixture in a medium

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such that a biological matrix is formed in vitro, and removing the matrix from the culture medium wherein the cell sample is obtained from a subject who will receive the biological matrix, the cell sample is blood; and the method further comprises adding a component that adds shape, structure or support to the matrix.

Vacanti teaches a biological matrix comprising mesenchymal cells (undifferentiated, precursor cells, or spore like cells) that are dissociated (or has cell fragments, lipids and polysaccharides) (abstract, col.2-3), struts (a component that adds shape, structure, support) (col.8-9) and a hydrogel (col.3-4). The matrix further includes cellular components such as fibrin, hyaluronic acid, collagen (col.4), fibronectin, laminin or glycosaminoglycans (col.8). Vacanti teaches the matrix is obtained by taking autologous cells (obtained from the recipient) and disrupting the cells via digestion the culturing the cells to form a matrix (col.2-3).

Although the reference does not specifically identify that the matrix is “living”, the matrix of the prior art is the same as claimed by applicant. Thus the matrix of the art must also be a living matrix.

Although Vacanti does not specifically identify the cells are obtained from blood, the claim is considered to be a product by process claim. Thus, the patentability of a product does not depend on its method of production. If the claimed product is the same or obvious from a product in the prior art (i.e. the product disclosed in the cited reference), the claim is unpatentable even though the reference product was made by a different process. When the prior art discloses a product which reasonably appears to be identical with or slightly different than the claimed product-by-process, rejections under 35 U.S.C 102 and/or 35 U.S.C 103 are proper.

(MPEP 2113)

3. Claims 18 – 19, 21 – 22, 24 – 25, 28 and 33 stand rejected under 35 U.S.C. 102(b) as being anticipated by Vacanti et al. (US 5885610).

Applicant claims a living biological matrix comprising a spore like cell, cell fragments, lipids and polysaccharides; a component that adds shape, structure, or support to the matrix; an antibiotic; and a cellular component selected from fibronectin, laminin, collagen, glycoprotein, thrombospondin, elastin, fibrillin, mucopolysaccharide, glycolipid, heparin sulfate, chondroitin sulfate, keratin sulfate, glycosaminoglycan, and hyaluronic acid. Applicant additionally claims a living biological matrix produced by obtaining a cell sample, disrupting the cell sample to create a mixture of cells and cellular debris, culturing the mixture in a medium such that a biological matrix is formed in vitro, and removing the matrix from the culture medium wherein the cell sample is obtained from a subject who will receive the biological matrix, the cell sample is blood; and the method further comprises adding a component that adds shape, structure or support to the matrix.

Vacanti teaches a biological matrix comprising parenchymal cells (undifferentiated, precursor cells, or spore like cells) that are dissociated (or has cell fragments, lipids and polysaccharides) (col.2-3), struts (a component that adds shape, structure, support) (col.5), cellular components such as collagen, fibronectin, laminin or glycosaminoglycans (col.5). The matrix further comprises antibiotics (examples). Vacanti teaches the matrix is obtained by taking autologous cells (obtained from the recipient) and disrupting the cells via digestion the culturing the cells to form a matrix (col.6).

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Although the reference does not specifically identify that the matrix is “living”, the matrix of the prior art is the same as claimed by applicant. Thus the matrix of the art must also be a living matrix.

Although Vacanti does not specifically identify the cells are obtained from blood, the claim is considered to be a product by process claim. Thus, the patentability of a product does not depend on its method of production. If the claimed product is the same or obvious from a product in the prior art (i.e. the product disclosed in the cited reference), the claim is unpatentable even though the reference product was made by a different process. When the prior art discloses a product which reasonably appears to be identical with or slightly different than the claimed product-by-process, rejections under 35 U.S.C 102 and/or 35 U.S.C 103 are proper.

(MPEP 2113)

### ***Response to Arguments***

Applicant argues that the references do not teach spore-like cells, but mesenchymal cells; that they do not teach a biological matrix with cells and cellular debris made by disrupting cells to produce the cellular materials; and that the cells of the references are living, not dead.

However, there arguments fail to persuade because the claims and specification fail to particularly define a spore-like cell as argued by applicant. The specification merely refers to the cells as undifferentiated cells or precursor cells (specification p.4). Since mesenchymal cells are undifferentiated, precursor cells, the reference appear to teach the claimed, spore-like cells.

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Regarding applicant's assertion that the references do not teach a biological matrix of cellular debris, it is noted that the claims do not require cellular debris made by a particular process, but requires cell fragments and/or cellular components. Regarding claim 24, this claim is treated as a product by process type claim. Specifically, if the claimed product is the same or obvious from a product in the prior art (i.e. the product disclosed in the cited reference), the claim is unpatentable even though the reference product was made by a different process. When the prior art discloses a product which reasonably appears to be identical with or slightly different than the claimed product-by-process, rejections under 35 U.S.C 102 and/or 35 U.S.C 103 are proper. (MPEP 2113)

Finally, regarding applicant's argument that the cells must be dead, it is noted that the claims do not require the cells to be dead, but are a living matrix, thus the argument is not commensurate in scope with the claims.

For these reasons and those stated in the rejections above, the claims stand rejected.

### ***Conclusion***

4. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

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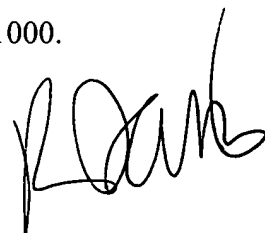
will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruth A. Davis whose telephone number is 571-272-0915. The examiner can normally be reached on M-F 7:00 - 2:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Ruth A. Davis  
Primary Examiner  
Art Unit 1651



October 13, 2006